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Supreme Court, U.S.
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No. 97-1125

In The

Supreme Court of the United States

October Term, 1997

SURGIDEV CORPORATION,

Petitioner,

v.

KATHRYN NIEHOFF,

Respondent.

On Petition For Writ Of Certiorari To The Supreme Court Of Kentucky

BRIEF IN OPPOSITION

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STATEMENT OF THE CASE AND MATERIAL PROCEEDINGS

Respondent Kathryn Niehoff, a seventy-three-year-old resident of Louisville, Kentucky, lost her left eye in 1990 as a result of the surgical removal of a defective intraocular lens (IOL) manufactured by petitioner Surgidev Corporation. The Surgidev "Style 10" IOL was unreasonably dangerous largely because its haptics – the wires on both sides of the IOL that fix it to the tissue of the eye – were designed as closed loops. According to evidence placed in the record below by Ms. Niehoff through expert opinion and published medical research, the movement of the closed loop against the tissue in the eye produced chronic inflammation, scarring around the loops, and an unacceptably high rate of various complications, including the type of corneal disintegration that afflicted Ms. Niehoff.

As Surgidev accurately recounts in its petition, Surgidev began selling the lens in 1978 pursuant to an "investigational device exemption" (IDE) obtained from the United States Food & Drug Administration under the 1976 Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.* It subsequently applied for premarket approval (PMA) of the lens and, in November 1982, the Ophthalmological Devices Panel of the FDA recommended approval of the application. Surgidev neglects to mention, however, that the panel conditioned its recommendation on the requirement that Surgidev distribute with its IOL's data pertaining to certain increased risks associated with the Style 10. According to Dr. Jack Drews, professor of ophthalmology at Washington University and a past president of the

American Intraocular Implant Society, if Surgidev had revealed this data to the ophthalmological community in 1982 – a year before Ms. Niehoff underwent implantation of the Style 10 – physicians experienced with implantation of IOL's would have recognized the implications of this data for the long-term safety of the Style 10 and would have publicly challenged its safety.

Surgidev never published the data and never obtained PMA. By 1985, articles began appearing in medical journals warning of sight-threatening complications emerging over time from use of closed-loop IOL's. By May 1988, when Surgidev "voluntarily" took the lens off the market because it was no longer selling, Surgidev had been selling the Style 10 as an "investigational device" for over ten years.

ARGUMENT

1. The Supreme Court Lacks Jurisdiction to Review the Judgment of the Kentucky Supreme Court Because it is Not Final.

Surgidev has invoked the Court's jurisdiction under 28 U.S.C. § 1257(a), which provides for review of "[f]inal judgments or decrees rendered by the highest court of a State in which a decision could be had . . . . " This Court recently revisited the meaning of "final judgment" under section 1257 in *Jefferson v. City of Tarrant*, 118 S. Ct. 481 (1997). The estate of a woman allegedly killed in a fire because of the negligence of a city fire department asked the Court to review a decision by the Alabama Supreme Court concluding that Alabama's wrongful death statute

limited recovery in a civil rights action to punitive damages. After concluding that state law barred any recovery on the estate's federal claims, the Alabama Supreme Court had remanded the case for further proceedings on the estate's claims under Alabama law. Despite having already granted certiorari to review the apparent conflict between state and federal law, this Court dismissed the writ for want of jurisdiction, finding that the Alabama Supreme Court's decision lacked the requisite finality under section 1257.

The Court observed that section 1257(a) "establishes a firm final judgment rule." 118 S. Ct. at 485. To merit review on certiorari, a state court judgment must be final "in two senses: it must be subject to no further review or correction in any other state tribunal; it must also be final as an effective determination of the litigation and not of merely interlocutory or intermediate steps therein. It must be the final word of a final court." *Id.* at 485-86 (*quoting Market Street R. Co. v. Railroad Comm'n*, 324 U.S. 548, 551 (1945)). Moreover, the finality rule "is not one of those technicalities to be easily scorned. It is an important factor in the smooth working of our federal system." *Id.* at 486 (*quoting Radio Station WOW, Inc. v. Johnson*, 326 U.S. 120, 124 (1945)).

Applying these precepts to the case before it, the Court concluded that the

> Alabama Supreme Court's decision was not a 'final judgment.' It was avowedly interlocutory. Far from terminating the litigation, the court answered a single certified question that affected only two of the four counts in petitioners' complaint.

> The court then remanded the case for further proceedings. Absent settlement or further dispositive motions, the proceedings on remand will include a trial on the merits of the state-law claims. In the relevant respect, this case is identical to *O'Dell v. Espinoza*, 456 U.S. 430, 102 S. Ct. 1865, 72 L.Ed.2d 237 (1982) (*per curiam*), where we dismissed the writ of certiorari for want of jurisdiction. *See ibid.* ("Because the Colorado Supreme Court remanded this case for trial, its decision is not final 'as an effective determination of the litigation.' " (citation omitted)).

Id. at 486.

Like the state court decision in *Jefferson*, the judgment of the Kentucky Supreme Court in this case is not final. It resolved the federal preemption issue in favor of Ms. Niehoff, then remanded the case for trial on her state tort claims. Thus, this case may well wind up once again in the Kentucky Supreme Court, or again in this Court on yet another petition for writ of certiorari. The finality doctrine precludes such piecemeal review.

Also like *Jefferson*, *see* 118 S. Ct. at 486-87, this case does not fall within any of the "exceptions" to finality discussed in *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469 (1975). It is not a case in which (1) the federal issue is conclusive or the outcome on remand is preordained; (2) the federal issue will survive and require decision regardless of the outcome of proceedings on remand; or (3) the federal issue cannot be reviewed after the conclusion of the proceedings on remand. *Cox Broadcasting*, 420 U.S. at 479-81. It is also not a case in which "a refusal to review the state court decision might seriously erode federal policy . . . . " *Id.* at 483. *See also Flynt v. Ohio*, 451 U.S. 619

(1981). As is discussed below, the FDA itself has determined that state tort suits are a corollary means for promoting federal health and safety objectives under the MDA.

2. A New Regulation Proposed By the FDA Makes Even More Explicit the FDA's Longstanding Narrow Approach To Federal Preemption Under the Medical Device Amendments.

Surgidev grounds its petition for certiorari primarily upon a split of authority among lower courts, state and federal, on the scope of federal preemption of state tort law under section 360k of the MDA. Most of the cases cited by Surgidev (at 14-17) predate this Court's decision in *Medtronic v. Lohr*, 116 S. Ct. 2240 (1996). Only two federal circuits and one state court of last resort (*see* Surgidev petition at 16 n. 36, 17 n. 42) have broadly preempted state tort claims under the MDA in the wake of *Lohr*. There may be a post-*Lohr* split of authority, but it is a split with few authorities thus far on either side. For this reason alone, it is premature for this Court to take up again, so soon after *Lohr*, the preemptive scope of section 360k.

Even more important, however, is that the FDA has initiated an effort, building upon *Lohr*, to resolve by regulation any remaining dispute over the appropriate scope of federal preemption under the MDA. On December 12, 1987, the FDA published its proposal for amending 21 C.F.R. § 808.1 – which already endorsed a narrow view of preemption, as this Court noted in *Lohr*, 116 S. Ct. at 2255-56 – to read as follows:

> (d)(11)(i) An FDA imposed requirement will preempt a State common law duty only when:
>
> (A) FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular device; and
>
> (B) The State common law, as interpreted and applied, imposes a substantive requirement applicable to the same particular device that is different from, or in addition to, FDA's counterpart requirement.
>
> (ii) FDA requirements that are applicable to devices in general, or that are established by means other than through regulation or order, should not result in preemption of State tort claims.
>
> (12) The clearance or approval of a particular device for marketing under section 510(k), 515, or 520(g) of the act does not in itself constitute the imposition of a specific substantive requirement with respect to that particular device that preempts a State or local requirement, including a standard of care imposed under State common law, with respect to the same device.

62 Fed. Reg. 65388.

The proposed new rule completely undermines the rationale of the post-*Lohr* decisions cited by Surgidev, such as *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), which doggedly cling to an expansive approach to preemption for all devices other than "substantially equivalent" devices introduced to the market through 21 U.S.C. § 510k (the type of device considered in *Lohr*). The Sixth Circuit concluded in *Martin* that the grant of an IDE automatically imposes preemption of

state tort challenges to the device's safety; the proposed rule, by contrast, imposes the same narrow, regulation-specific analysis on *all* types of devices covered by the MDA. As the FDA explained in the commentary accompanying the rule, "FDA's action in clearing a product for marketing or granting an application for a PMA or an IDE signifies that the manufacturer's proposal for marketing or use of the device in question satisfies the relevant statutory and regulatory criteria for the clearance, approval, or exemption. It does not signify, however, that Congress or FDA has established a specific Federal requirement (e.g., with respect to the design of the device) that supplants a State common law duty." 62 Fed. Reg. 65387.

The Sixth Circuit also opined that allowance of state tort claims would "impede the implementation and enforcement of specific federal requirements." 105 F.3d at 1099. The new rule embodies the longstanding disagreement of the FDA – the agency responsible for such implementation and enforcement – with this false premise. "FDA believes that its general regulatory review and approval processes provide a significant measure of protection against the marketing of dangerous or defective medical devices. FDA does not believe, however, that those processes can guarantee the safety of such devices. Accordingly, compliance with general FDA requirements should not broadly preempt state common law remedies, which provide an important (and frequently the only) mechanism for persons to seek redress for injuries resulting from defective medical devices." 62 Fed. Reg. 65387.

Finally, the Sixth Circuit believed that the promulgation of *any* device-specific regulations by the FDA, such

as those in 21 C.F.R. Part 813 pertaining to IOL's, justified preemption of *any* state tort claim against that device. The FDA has also put this notion to rest. "[E]ven if FDA has imposed specific Federal requirements respecting a particular medical device, those requirements do not preempt all State common law claims respecting the device. Section 521 of the Act provides for preemption only if the State common law duties are 'different from, or in addition to,' the specific Federal requirements." 62 Fed. Reg. at 65387. This is, of course, precisely what Justice Breyer, whose concurrence completed the majority, was saying in his "one-inch wire" analogy in *Lohr*. *See* 116 S. Ct. at 2260.

This Court admonished in *Lohr* that the FDA's view should be given "substantial weight" in determining the reach of the MDA's preemption provision. 116 S. Ct. at 2256. According to the Court, "Congress has given the FDA a unique role in determining the scope of § 360k's preemptive effect" because "in most cases a state law will be preempted only to the extent that the FDA has promulgated a relevant federal 'requirement.' " *Id.* at 2255. "Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " *Id.* (*quoting Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). *See also id.* at 2260-61 (Breyer, J, concurring).

Undoubtedly, the FDA's proposed new rule will serve as convincing authority for future judicial inquiries into the scope of preemption under section 360k of the

MDA. This Court should permit the new rule and its accompanying commentary to percolate through the state and federal courts before undertaking another review of this issue.

3. The Kentucky Supreme Court Correctly Determined That Ms. Niehoff's State Tort Claims Do Not Conflict With Any Device-Specific Federal Regulations.

The majority of this Court in *Lohr* – Justice Stevens' plurality plus Justice Breyer's concurrence – established that federal regulations under the MDA preempt state tort claims only where there is an "actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state tort suit . . . . " 116 S. Ct. at 261 (Breyer, J, concurring). The FDA, on whose narrow interpretation of preemption the *Lohr* majority relied, has now further endorsed in its proposed new rule this specific comparison of federal requirement to state claim. "In accordance with the principles that FDA articulated in its 1978 regulations, to which the Supreme Court in *Lohr* held that deference is owed, FDA believes that, as a general matter, an FDA-imposed requirement will preempt a State common law duty only when: (1) FDA has expressly imposed, by regulation or order, a specific substantive requirement applicable to a particular medical device; and (2) the State common law, as interpreted and applied, imposes a substantive requirement applicable to the same particular medical device that is different from, or in addition to, FDA's counterpart requirement." 62 Fed. Reg. 65387.

This is exactly the analysis undertaken by the Kentucky Supreme Court in this case. *See Niehoff v. Surgidev Corp.*, 950 S.W.2d 816, 812 (Ky. 1997) (Surgidev petition appendix 15a). Ms. Niehoff alleged that the Style 10 was defective because of its closed-loop design; no FDA regulation required a closed-loop design, or, indeed, any particular design. Ms. Niehoff alleged that the Style 10 was unreasonably dangerous, and Surgidev was negligent, because Surgidev failed to provide the warning recommended by the FDA advisory panel in 1982; federal regulations did not preclude, but encouraged, dissemination of scientific data. *See* 21 C.F.R. § 813.50. Ms. Niehoff claimed that Surgidev negligently violated various federal regulations; even the dissenters in *Lohr* agreed that federal law would not preempt such claims. 116 S. Ct. at 2264 (O'Connor, J).

In the end, this Court should not review the decision by the Kentucky Supreme Court because that Court reached the correct result through reasoning in full accord with the *Lohr* majority and the FDA's interpretation of section 360k of the MDA.

CONCLUSION

For all of the forgoing reasons, respondent Kathryn Niehoff respectfully requests the United States Supreme Court to deny Surgidev's petition for writ of certiorari.

Dated February 9, 1998

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